

**510(k) Summary:****JUN - 8 2001**

This summary is provided as part of this Premarket Notification in compliance with 21CFR, Section 807.92.

Submitters name: B-K Medical A/S

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Contact person: Villy Braender, Quality Assurance Mnager

Date prepared: 4. May, 2000

Trade name: Ultrasound Scanner Type 2102

Common name: Diagnostic Ultrasound System

Classification names:

Ultrasonic Pulsed Echo Imaging System (90 IYO, CFR 892.1560)

Ultrasonic Pulsed Doppler Imaging System (90 IYN, CFR 892.1560)

Diagnostic Ultrasonic Transducer (90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:

Siemens Medical Systems: Sonoline Elegra Diagnostic Ultrasound System (K980557)

**Device description:**

2102 supports the following scanning modes and combinations thereof:

B-mode, M-mode, PWD mode and CFM mode. Tissue harmonic imaging.

An optional ECG signal can be superimposed the ultrasound information in all modes and mode combinations.

The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.

The system can guide biopsy- and puncture needles.

**Transducers**

Transducers are linear and convex arrays and mechanical sector.

The patient contact materials comply with ISO10993-1

All transducers used together with 2102 are Track 3 transducers.

**Acoustic output**

The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e.  $Ispta \leq 720 \text{ mW/cm}^2$  and  $MI \leq 1.9$  (Track 3, non ophthalmic).

The Thermal Index values are maximum 6.0, i.e.  $TI \leq 6.0$

**Clinical measurement accuracy.**

Clinical measurements and calculations are described and accuracies are provided in the User Guide.

**Thermal, mechanical and electrical safety.**

The scanner 2102 has been tested by a recognized, certified body according to IEC 60601-1.

**Acoustic Output Reporting**

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

**Intended use.**

See comparison below

**Technological characteristics compared to the predicate device.**

The predicate device has the same major technological characteristics as the subject device, see comparison below.

Comparison with K980557, Sonoline Elegra (Siemens Medical Systems).

|                                  | Type 2102 in this application  | K980557, Sonoline Elegra   |
|----------------------------------|--|--|
| Intended uses                    | Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Obstetrics, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal (superficial, conventional), Peripheral Vascular | General Radiology, Abdominal, Intraoperative, Small parts, transcranial, OB/GYN, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular |
| General device description       | B,M, Color, PW and combination modes. Tissue harmonic imaging. Track 3 (Index display). Measurements   | B,M Color, PW, CW and combination modes. Track 3 (Index display). Measurements.  |
| Acoustic output                  | $Ispta \leq 720 \text{ mW/cm}^2$ and $MI \leq 1.9$ (Track 3, non ophthalmic). $TI \leq 6.0$  | Not in 510(k) summary, except that it has index display according to Display standard.   |
| General safety and effectiveness | UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard, EN/ISO 10993-1   | UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard   |
| Labeling                         | Please refer to section 4.8  | Not in 510(k) summary)   |

Conclusion: The device 2102 in this application has similar intended uses, and in particular the subject for the application, musculo-skeletal is the same. Also both devices have been previously cleared for 'small parts' (organs), an indication very close to 'musculo-skeletal, superficial'). B-K Medical A/S therefore believes, that 2102 is substantially equivalent to K980557.



JUN - 8 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Villy Braender  
Official Correspondent  
B&K Medical A/S  
Sandoften 9  
DK-2820, Gentofte  
Denmark

Re: K011417  
Trade Name: Ultrasound Scanner Type 2102  
Regulatory Class: II/21 CFR 892.1560  
Product Code: 90 IYO  
Dated: May 4, 2001  
Received: May 9, 2001

Dear Mr. Braender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Type 2102, as described in your premarket notification:

Transducer Model Number

8660  
8664  
8804  
8805

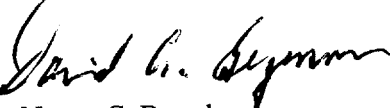
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

*for* 

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2102  
Transducer: 8660

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application      |                              | Mode of Operation |   |     |     |                  |                       |                     |
|---------------------------|------------------------------|-------------------|---|-----|-----|------------------|-----------------------|---------------------|
| General<br>(Track I Only) | Specific<br>(Tracks I & III) | B                 | M | PWD | CWD | Color<br>Doppler | Combined<br>(Specify) | Other*<br>(Specify) |
| Ophthalmic                | Ophthalmic                   |                   |   |     |     |                  |                       |                     |
| Fetal Imaging<br>& Other  | Fetal                        |                   |   |     |     |                  |                       |                     |
|                           | Abdominal                    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Specify)    | P                 | P | P   |     | P                | P 1)                  | P 2)                |
|                           | Intra-operative (Neuro)      |                   |   |     |     |                  |                       |                     |
|                           | Laparoscopic                 |                   |   |     |     |                  |                       |                     |
|                           | Pediatric                    | P                 | P | P   |     | P                | P 1)                  | P 2)                |
|                           | Small Organ (Specify)        | P                 | P | P   |     | P                | P 1)                  | P 2) + 3)           |
|                           | Neonatal Cephalic            |                   |   |     |     |                  |                       |                     |
|                           | Adult Cephalic               |                   |   |     |     |                  |                       |                     |
|                           | Trans-rectal                 |                   |   |     |     |                  |                       |                     |
|                           | Trans-vaginal                |                   |   |     |     |                  |                       |                     |
|                           | Trans-urethral               |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (non-Card.)     |                   |   |     |     |                  |                       |                     |
|                           | Musculo-skel. (Conventional) | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Musculo-skel. (Superficial)  | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Intra-luminal                |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Cardiac                   | Cardiac Adult                |                   |   |     |     |                  |                       |                     |
|                           | Cardiac Pediatric            |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (Cardiac)       |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Peripheral<br>Vessel      | Peripheral vessel            | P                 | P |     |     | P                | P 1)                  | P 2) + 3)           |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |

N= new indication; P= previously cleared by FDA(K991937); E= added under Appendix E

\*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system

Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

1) Mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Amplitude Doppler.

3) Tissue Harmonic Imaging

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number

K011417

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2102  
Transducer: 8664

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application      |                              | Mode of Operation |   |     |     |                  |                       |                     |
|---------------------------|------------------------------|-------------------|---|-----|-----|------------------|-----------------------|---------------------|
| General<br>(Track I Only) | Specific<br>(Tracks I & III) | B                 | M | PWD | CWD | Color<br>Doppler | Combined<br>(Specify) | Other*<br>(Specify) |
| Ophthalmic                | Ophthalmic                   |                   |   |     |     |                  |                       |                     |
| Fetal Imaging<br>& Other  | Fetal                        |                   |   |     |     |                  |                       |                     |
|                           | Abdominal                    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Specify)    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Neuro)      |                   |   |     |     |                  |                       |                     |
|                           | Laparoscopic                 |                   |   |     |     |                  |                       |                     |
|                           | Pediatric                    | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Small Organ (Specify)        | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Neonatal Cephalic            |                   |   |     |     |                  |                       |                     |
|                           | Adult Cephalic               |                   |   |     |     |                  |                       |                     |
|                           | Trans-rectal                 |                   |   |     |     |                  |                       |                     |
|                           | Trans-vaginal                |                   |   |     |     |                  |                       |                     |
|                           | Trans-urethral               |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (non-Card.)     |                   |   |     |     |                  |                       |                     |
|                           | Musculo-skel. (Conventional) | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Musculo-skel. (Superficial)  | N                 | N |     |     |                  | N(B+M)                |                     |
| Cardiac                   | Intra-luminal                |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
|                           | Cardiac Adult                |                   |   |     |     |                  |                       |                     |
|                           | Cardiac Pediatric            |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (Cardiac)       |                   |   |     |     |                  |                       |                     |
| Peripheral<br>Vessel      | Other (Specify)              |                   |   |     |     |                  |                       |                     |
|                           | Peripheral vessel            | E                 | E | E   |     | E                | E 1)                  | E 2)                |

N= new indication; P= previously cleared by FDA(K991937); E= added under Appendix E

\*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

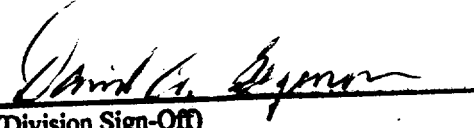
1) Mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Amplitude Doppler

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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K011417

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2102  
Transducer: 8804

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application      |                              | Mode of Operation |   |     |     |                  |                       |                     |
|---------------------------|------------------------------|-------------------|---|-----|-----|------------------|-----------------------|---------------------|
| General<br>(Track I Only) | Specific<br>(Tracks I & III) | B                 | M | PWD | CWD | Color<br>Doppler | Combined<br>(Specify) | Other*<br>(Specify) |
| Ophthalmic                | Ophthalmic                   |                   |   |     |     |                  |                       |                     |
| Fetal Imaging<br>& Other  | Fetal                        |                   |   |     |     |                  |                       |                     |
|                           | Abdominal                    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Specify)    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Neuro)      |                   |   |     |     |                  |                       |                     |
|                           | Laparoscopic                 |                   |   |     |     |                  |                       |                     |
|                           | Pediatric                    | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Small Organ (Specify)        | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Neonatal Cephalic            |                   |   |     |     |                  |                       |                     |
|                           | Adult Cephalic               |                   |   |     |     |                  |                       |                     |
|                           | Trans-rectal                 |                   |   |     |     |                  |                       |                     |
|                           | Trans-vaginal                |                   |   |     |     |                  |                       |                     |
|                           | Trans-urethral               |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (non-Card.)     |                   |   |     |     |                  |                       |                     |
|                           | Musculo-skel. (Conventional) | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Musculo-skel. (Superficial)  | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Intra-luminal                |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Cardiac                   | Cardiac Adult                |                   |   |     |     |                  |                       |                     |
|                           | Cardiac Pediatric            |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (Cardiac)       |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Peripheral<br>Vessel      | Peripheral vessel            | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |

N= new indication; P= previously cleared by FDA(K991937); E= added under Appendix E

\*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

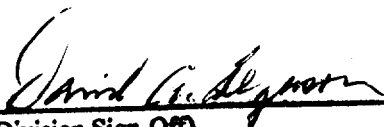
1) mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Amplitude Doppler

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K011417

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 2102  
Transducer: 8805

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application      |                              | Mode of Operation |   |     |     |                  |                       |                     |
|---------------------------|------------------------------|-------------------|---|-----|-----|------------------|-----------------------|---------------------|
| General<br>(Track I Only) | Specific<br>(Tracks I & III) | B                 | M | PWD | CWD | Color<br>Doppler | Combined<br>(Specify) | Other*<br>(Specify) |
| Ophthalmic                | Ophthalmic                   |                   |   |     |     |                  |                       |                     |
| Fetal Imaging<br>& Other  | Fetal                        |                   |   |     |     |                  |                       |                     |
|                           | Abdominal                    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Specify)    |                   |   |     |     |                  |                       |                     |
|                           | Intra-operative (Neuro)      |                   |   |     |     |                  |                       |                     |
|                           | Laparoscopic                 |                   |   |     |     |                  |                       |                     |
|                           | Pediatric                    |                   |   |     |     |                  |                       |                     |
|                           | Small Organ (Specify)        | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Neonatal Cephalic            |                   |   |     |     |                  |                       |                     |
|                           | Adult Cephalic               |                   |   |     |     |                  |                       |                     |
|                           | Trans-rectal                 |                   |   |     |     |                  |                       |                     |
|                           | Trans-vaginal                |                   |   |     |     |                  |                       |                     |
|                           | Trans-urethral               |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (non-Card.)     |                   |   |     |     |                  |                       |                     |
|                           | Musculo-skel. (Conventional) | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Musculo-skel. (Superficial)  | N                 | N |     |     |                  | N(B+M)                |                     |
|                           | Intra-luminal                |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Cardiac                   | Cardiac Adult                |                   |   |     |     |                  |                       |                     |
|                           | Cardiac Pediatric            |                   |   |     |     |                  |                       |                     |
|                           | Trans-esoph. (Cardiac)       |                   |   |     |     |                  |                       |                     |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |
| Peripheral<br>Vessel      | Peripheral vessel            | E                 | E | E   |     | E                | E 1)                  | E 2)                |
|                           | Other (Specify)              |                   |   |     |     |                  |                       |                     |

N= new indication; P= previously cleared by FDA(K991937); E= added under Appendix E

\*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes.

1) mode combinations: B, B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude (power) Doppler)

2) Amplitude Doppler

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

*David A. Seymour*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number R011417